corresponding PCT application PCT/US00/17405 that was indicated as meeting novelty and non-obviousness in the IPER issued November 20, 2001.

Objections to the Specification

The specification was objected to for informalities. The typographical error on page 7 was addressed in Applicants' amendment filed March 8, 2002. The typographical error on page 16 has been addressed in the present amendment.

Claim Rejections - 35 U.S.C. §102

Claims 1-14 were rejected under 35 U.S.C. §102(b) based upon public use or sale of the invention.

As an initial matter, Applicants submit that none of the cited references disclose any public use or sale of the invention prior to the critical date.

Public Use

The alleged public use of the invention revolves around the clinical trial (i.e., study) described in *Crit. Care Med. 2000, 28:12*. However, as clearly stated on page 3925 of that reference document, the clinical trial involved monitoring of a *single* "10-bed surgical ICU", whereas the present invention claims monitoring of "a *plurality* of health care locations" (claim 1) or "*plurality* of ICU's" (claim 11), such that the clinical trial monitoring of a single surgical ICU was not a use of the presently claimed invention.

With regard to this use being applicable to a rejection under 35 U.S.C. §103, Applicants submit that the described clinical trial was an "Acceptable Activity" of experimental use as defined in Section 2133.03(e) of the Manual of Patent Examining Procedure.

The basic test is that experimentation must be the primary purpose and any commercial exploitation must be incidental. If the use or sale was experimental, there is no bar under 35 U.S.C. 102(b). "A use or sale is experimental for purposes of section 102(b) **if it represents a bona fide effort** to perfect the invention or **to ascertain whether it will answer its intended purpose**.

By definition, the present clinical trial or "study" was clearly for the purpose of ascertaining whether remote monitoring of an ICU would provide adequate care to patients. The study had no commercial exploitation as it was performed by the Johns Hopkins University School of Medicine in the affiliated hospital. The study therefore clearly falls within this acceptable use, especially when compared to the factors below.

The factors indicative of an experimental purpose were set forth by the Supreme Court in *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1878):

(A) the **nature of the invention was such that any testing had to be to some extent public**;

(B) **testing had to be for a substantial period of time**;

(C) testing was conducted **under the supervision and control of the inventor**; and

(D) **the inventor regularly inspected the invention during the period of experimentation.**

Each of these factors were present in this case. The nature of ICU monitoring means that it must be performed in a real ICU. The testing was for periods sufficient to gather data. The inventors participated in and supervised the trial.

Supreme Court decisions subsequent to *City of Elizabeth* identify other significant factors which may be determinative of experimental purpose:

(E) **extent of any** obligations **or limitation** placed on a user during a period of experimental activity, as well as the extent of an testing actually performed during such period (*Egbert v. Lippmann*, 104 U.S. 333 (1881));

(F) **length of time and number of cases** in which experimental activity took place, viewed in light of what was reasonably necessary for an alleged experimental purpose (*International Tooth Crown Co. v. Gaylord*, 140 U.S. 55 (1891)).

Both of these factors were present since the trial was limited in scope (a single surgical ICU) and time.

Other judicial opinions have supplemented these factors by looking to the extent of any:

(G) explicit or implicit obligations placed upon a user to supply an inventor with the results of any testing conducted during an experimental period and the **extent of inquiry made by the inventor regarding the testing** (*Robbins Co. v. Lawrence Mfg. Co.*, 178 USPQ 577, 583 (9th Cir. 1973));

(H) a **doctor-patient relationship** where the inventor/doctor conducted the experimentation (TP Labs. Inc. v. Professional Positioners, Inc., 724 F.2d 965, 971, 220 USPQ 577, 582 (Fed. Cir. 1984).

Again, the described study was solely to collect patient data to compare remote-monitored patient care with ordinary patient care and involved the doctor-patient relationship since doctors conducted the study with the patients.

In view of these above-mentioned factors, Applicants submit that there is overwhelming evidence that the described study was a "Permitted Activity" under M.P.E.P. 2133.03(e).

B

On Sale and Other Disclosures

Although the body of the rejection in the Office Action only referred to "prior public use," the Office Action requested further information regarding sales, solicitations, and disclosures.

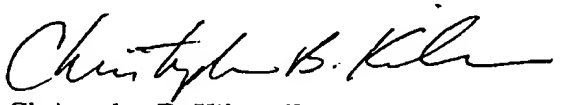
As submitted herewith, Applicants claim the benefit of their provisional application filing date of June 23, 1999, which makes the critical date June 23, 1998 for any sales, solicitations, and disclosures.

Additionally, as submitted in Exhibit A (attached hereto), VISICU, INC., formerly IC-USA, INC. was not incorporated until July of 1998, which was after this critical date. Therefore, VISICU, INC. (IC-USA, INC.) was not engaged in any sales or public marketing until after the critical date.

Conclusion

For the reasons cited above, Applicants submit that claims 1-11 and 13-14 are in condition for allowance and requests reconsideration of the application. If there remain any issues that may be disposed of via a telephonic interview, the Examiner is kindly invited to contact the undersigned at the local exchange given below.

Respectfully submitted,



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